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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,214	03/30/2001	Michael Robert Dunlavey	261/049	6076

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EXAMINER
SHAAWAT, MUSSA

ART UNIT	PAPER NUMBER
2128	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application N .		Applicant(s)
Office Action Summary	09/823,214		DUNLAVEY ET AL.
	Examiner		Art Unit
	Mussa A Shaawat		2128

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>30 March 2001</u>.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
   closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>1-26</u> is/are pending in the application.

   4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>1-26</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on <u>30 March 2001</u> is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

   Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   a) ☐ All b) ☐ Some * c) ☐ None of:

   1. ☐ Certified copies of the priority documents have been received.

   2. ☐ Certified copies of the priority documents have been received in Application No. _____.

   3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
      application from the International Bureau (PCT Rule 17.2(a)).

   * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
   Paper No(s)/Mail Date <u>17 September 2001</u>.

4) ☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

1.   This action is responsive to application # 09/823,214, filed on March 30, 2001. Claims

1-26 are presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

(e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the
United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by
another filed in the United States before the invention by the applicant for patent, except that an international application
filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed
in the United States only if the international application designated the United States and was published under Article
21(2) of such treaty in the English language.

2.   Claims 1-4, and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated John A.

Keane US Patent No. (6,381,562) referred to hereinafter as Keane.

As to claim 1, KEANE teaches a method for pharmacological computational model

construction, comprising:(a) presenting a graphical user interface having a plurality of objects,

each object representing one or both of a pharmacokinetic element and a pharmacodynamic

element (see col.13 lines 40-45, and col.16 lines 15-25, user enters drug characteristics which

corresponds to pharmacodynamic elements);

(b) Receiving instructions via the graphical user interface for connection of at least two of

the objects (see col.16 lines 27-45, user selects organ elements as an input to fluid flow model);

(c) Displaying the at least two objects connected in accordance with the received

instructions (see col.16 lines 46-51, elements are stored and are retrieved y so that they would be

accessible to the user);

(d) Converting the at least two connected objects into equations corresponding to the pharmacokinetic and pharmacodynamic elements represented by the at least two connected objects, wherein the converting step (d) occurs substantially coincident with the object displaying step (c) (see col.16 lines 61-67, col.17 lines 1-2, and col.18 lines 11-43); and

(e) Displaying the equations on the graphical user interface substantially coincident with the object-displaying step (c) (see col.23 lines 50-56, display the result of the model to the user).

As to claim 2, KEANE teaches a method of claim 1, wherein the converting step (d) comprises: (f) converting the at least two connected objects into an internal format (col.17 lines 33-52); and (g) converting the internal format into a surface syntax (see col.6 64 –67, col.7 lines 1-2, and col.17 lines 3-15).

As to claim 3, KEANE teaches a method of claim 2, wherein the surface syntax represents differential equations in an integrator equals rate expression format (see col.6 64 –67, col.7 lines 1-2, and col.17 lines 3-15).

As to claim 4, KEANE teaches a method of claim 2, wherein the objects comprise one of more of compartment blocks, flow blocks, response blocks, and formulation blocks (see col.16 lines 27-45).

As to claims 14-15, the limitations of claims 14-15 are the same limitations of claims 1-2; therefore they are rejected based on the same rationale, supra.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3.   Claims 5-13, and 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over

John A. Keane US Patent No. (6,381,562) referred to hereinafter as Keane in view of Dwayne

Westenskow US Pub. No. (US 2003/0156143A1) referred to hereinafter as Westenskow.

As to claim 5, KEANE teaches a method for pharmacological computational model

construction, comprising: (a) presenting a graphical user interface having a plurality of objects,

each object representing one or both of a pharmacokinetic element and a pharmacodynamic

element (see col.13 lines 40-45, and col.16 lines 15-25, user enters drug characteristics which

corresponds to pharmacodynamic elements);

(b) Receiving instructions via the graphical user interface for connection of at least two of

the objects (see col.16 lines 27-45, user selects organ elements as an input to fluid flow model);

(c) Displaying the at least two objects connected in accordance with the received

instructions (see col.16 lines 46-51, elements are stored and are retrieved y so that they would be

accessible to the user);

(d) Converting the at least two connected objects into equations corresponding to the

pharmacokinetic and pharmacodynamic elements represented by the at least two connected

objects, wherein the converting step (d) occurs substantially coincident with the object

displaying step (c) (see col.16 lines 61-67, col.17 lines 1-2, and col.18 lines 11-43); and

(e) Interpreting the internal format to generate a time-based simulation including

calculation of one or more selected variables (see col.6 64 –67, col.7 lines 1-2, and col.17 lines

3-15);

However Keane does not expressly teach plotting one or more selected variables in a graph and update the graph.

Westenskow teaches plotting one or more selected variables in a graph and updating the graph (see Page 14 Paragraph [0160], et-seq).

It would have been obvious to one of the ordinary skill in the art at the time of the applicant's invention to combine the teaching of Westenskow to Keane's method because Westenskow's teaching of potting one or more variables in a graph would allow users of Keane's method to quickly and accurately analyze the complex and rapidly changing relationship between various data. Moreover, presenting the information to a user in a graphical form is easier for the user to correlate, manipulate and use the information.

As to claim 6, KEANE teaches a method of claim 5, further comprising: (h) receiving commands via the graphical user interface to modify at least one of the one or more selected variables (see col.16 lines 27-45, user selects organ elements as an input to fluid flow model); and

However Keane does not expressly teach plotting one or more selected variables in a graph and update the graph.

Westenskow teaches plotting one or more selected variables in a graph and updating the graph (see Page 14 Paragraph [0160], et-seq).

It would have been obvious to one of the ordinary skill in the art at the time of the applicant's invention to combine the teaching of Westenskow to Keane's method because Westenskow's teaching of potting one or more variables in a graph would allow users of Keane's method to quickly and accurately analyze the complex and rapidly changing relationship

between various data. Moreover, presenting the information to a user in a graphical form is easier for the user to correlate, manipulate and use the information.

As to claim 7, KEANE teaches a method of claim 6, wherein the modifying step (i) comprises revising the internal format (see col.6 64 –67, col.7 lines 1-2, and col.17 lines 3-15).

As to claim 8, KEANE teaches a method of claim 6, wherein one or more of the one or more selected variables depend upon a random variable, wherein the interpreting step (e) generates a value for the random variable upon each repetition (see col.6 64 –67, col.7 lines 1-2, and col.17 lines 3-15),

However Keane does not expressly teach plotting one or more selected variables in a graph and update the graph.

Westenskow teaches plotting one or more selected variables in a graph and updating the graph (see Page 14 Paragraph [0160], et-seq).

It would have been obvious to one of the ordinary skill in the art at the time of the applicant's invention to combine the teaching of Westenskow to Keane's method because Westenskow's teaching of potting one or more variables in a graph would allow users of Keane's method to quickly and accurately analyze the complex and rapidly changing relationship between various data. Moreover, presenting the information to a user in a graphical form is easier for the user to correlate, manipulate and use the information.

As to claim 9, KEANE teaches a method of claim 6, wherein the internal format comprises a parse tree (see col.6 64 –67, col.7 lines 1-2, and col.17 lines 3-15, and Figure 8).

As to claim 10, KEANE teaches a method of claim 6, wherein the one or more selected variables comprise at least two selected variables (see col.13 lines 40-59),

However Keane does not expressly teach plotting one or more selected variables in a

graph and update the graph.

Westenskow teaches plotting at least one selected variable versus another selected

variable (see Page 14 Paragraph [0160], et-seq).

It would have been obvious to one of the ordinary skill in the art at the time of the

applicant's invention to combine the teaching of Westenskow to Keane's method because

Westenskow's teaching of potting at least one selected variable versus another selected variable

would allow users of Keane's method to quickly and accurately analyze the complex and rapidly

changing relationship between various data. Moreover, presenting the information to a user in a

graphical form is easier for the user to correlate, manipulate and use the information.

As to claim 11, KEANE teaches one or more selected variables (see col.13 lines 40-59).

However Keane does not expressly teach plotting one or more selected variables versus time.

Westenskow teaches plotting at least one selected variable versus time (see Page 14

Paragraph [0160], et-seq).

It would have been obvious to one of the ordinary skill in the art at the time of the

applicant's invention to combine the teaching of Westenskow to Keane's method because

Westenskow's teaching of potting at least one selected variable versus time would allow users of

Keane's method to quickly and accurately analyze the complex and rapidly changing relationship

between various data. Moreover, presenting the information to a user in a graphical form is

easier for the user to correlate, manipulate and use the information.

As to claim 12, KEANE teaches a method of claim 5, further comprising: (j) translating

the internal format into text strings representing equations, the equations corresponding to the

respective pharmacokinetic and pharmacodynamic elements represented by the two or more

connected objects (see col.6 64 –67, col.7 lines 1-2, and col.17 lines 3-15); and (k) displaying the

text strings substantially coincident with the object displaying step (c) (see col.23 lines 50-56,

display the result of the model to the user).

As to claim 13, KEANE teaches a method of claim 12, wherein the objects comprise one

or more of compartment blocks, flow blocks, response blocks, and formulation blocks (see

col.16 lines 27-45).

As to claim 16, the limitations of claim 16 are the same limitations of claim 5; therefore

they are rejected based on the same rationale, supra.

As to claim 17, the limitations of claim 1 are the same limitations of claim 6; therefore

they are rejected based on the same rationale, supra.

As to claim 18, the limitations of claim 18 are the same limitations of claim 8; therefore

they are rejected based on the same rationale, supra.

As to claim 19, the limitations of claim 19 are the same limitations of claim 11; therefore

they are rejected based on the same rationale, supra.

As to claim 20, the limitations of claim 20 are the same limitations of claim 12; therefore

they are rejected based on the same rationale, supra.

As to claim 21, the limitations of claim 21 are the same limitations of claim 5; therefore

they are rejected based on the same rationale, supra.

As to claim 22, the limitations of claim 22 are the same limitations of claim 6; therefore

they are rejected based on the same rationale, supra.

As to claim 23, the limitations of claim 23 are the same limitations of claim 8; therefore they are rejected based on the same rationale, supra.

As to claim 24, the limitations of claim 24 are the same limitations of claim 11; therefore they are rejected based on the same rationale, supra.

As to claim 25, KEANE teaches one or more selected variables (see col.13 lines 40-59). However Keane does not expressly teach plotting one or more selected variables using a different color.

Westenskow teaches plotting at least one selected variable using color (see Page 14 Paragraph [0160], et-seq, color bands on the graph shows the effect of individual drugs which corresponds to variables being plotted on a graph using different colors).

It would have been obvious to one of the ordinary skill in the art at the time of the applicant's invention to combine the teaching of Westenskow to Keane's method because Westenskow's teaching of potting at least one selected variable using different colors indicators for each variable would allow users of Keane's method to quickly and accurately analyze the complex and rapidly changing relationship between various data. Moreover, presenting the information to a user in a graphical form is easier for the user to correlate, manipulate and use the information.

As to claim 26, the limitations of claim 26 are the same limitations of claim 12; therefore they are rejected based on the same rationale, supra.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Keane Pub. No. (US 2002/0120431A1) configurable Bio-transport system simulator.

- Comanor US Patent No. (5,860,917) method and apparatus for predicting therapeutic outcomes.

- Weininger US Patent No. (5,434,796) method and apparatus for designing molecules with desired properties by evolving successive populations.

- Garner Pub. No. (2204/0093331) computer program products, systems and methods for information discovery and relational analysis.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mussa A Shaawat whose telephone number is (571) 272-3785. The examiner can normally be reached on Monday-Friday (8:30am to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jean R Homere can be reached on (571) 272-3780. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mussa Shaawat
Patent Examiner
December 9, 2004

JEAN R. HOMERE
PRIMARY EXAMINER